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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/684,836
Filing Date: October 15, 2003
Appellant(s): MORITA ET AL.

Stephen Becker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/21/07 appealing from the Office action mailed 6/22/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

JP-3221095 B

JP-2000-107758

JP-63-028406

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,8 and 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms (L) and (Y) have no antecedent basis.

Claims 1,8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

Applicant's arguments and supporting evidence was considered, and accordingly, the 'maximum fibril length' is being considered the same as the 'maximum length of pores'. It is also clarified that the term 'maximum length of pores' is interpreted as the cross-sectional length of pore at the filtration layer surface, in the light of specification page 15 lines 21-23, and applicant's arguments of 6/5/06

The omitted structural cooperative relationships are: the relationship between the variables X, Y and mean maximum length of pore, and the plot of the ten points. This claim language does not relate it to any specific structural characteristic of the filtration layer. This limitation is indefinite because it really does not define any metes and bounds for the claimed structure. Claim language includes any particle size that would be trapped to 90% or greater.

For example, in applicant's comparative example 1, with L=15 μm and X = 0.2 μm, the RFL or Y value of 75 would not fit within the claimed region. However, if one were filtering the particles of Example 2, i.e., 2 μm, with the same filtration layer, then the RFL of 7.5 would fall within the region as shown in the art rejection below. Therefore, the filtration layer of the same structure is found meeting the claim in one instance and not meeting the claim in another instance, which leads to indefiniteness.

In the arguments submitted on 6/6/07, applicant stated that:

> As noted above, "X" is merely a title/name which identifies a particular grade of a filter which has been standardized in the industry. One of ordinary skill in the art will recognize that X=2 μm and X=.2 μm, by definition, refer to different filters. In this regard, the Examiner's example on page 3, lines 3-8 of the outstanding Office Action purportedly evidencing why claim 1 is indefinite, is based on the false assumption that X=2 μm and X=.2 μm can refer to the same membrane.

In these arguments' applicant is now attempting to define (X) as the micron-rating of the membrane (filtration layer). However, Claim 1 defines (X) as diameter of particles captured with a trapping ratio of 90% or more. So, if the filtration layer captures 0.2 μm particles to >90%, it would definitely capture 2 μm particles to greater than 90%. The office must consider what is presented in the claims and what is disclosed by the applicant; not what the industry standard says.

In addition, Applicant's example 2 at paragraph [0104] of the Pre-Grant Publication has (L) as 40 μm, and particle size (X) as 2 μm. For this, (Y) will be 20, and this support does not fall in the region (M) of figure 1. However, in paragraph [0105], with the porous expanded PTFE sheet applied as the filtration layer, the (X) value used is 5 µm. (L) is 15 µm, and the corresponding (Y) value of 3 would fall within the region (M). There is no rationale for using the 5 µm particle for this part of the experiment. ***Since the support layer has a catching performance of 90% for 2 µm particles, after addition of the filtration layer, the filter should still capture the 2 µm particles to greater than 90%.*** Then why would the experiment be conducted with 5 µm particles**? This shows that "X" is ill-defined in the claims.** (Specification, page 34, line 17 – page 35, line 10).

For examination, the values of X and Y are considered as optimizable variables for increasing filter flux without increasing the fouling.

Claim Rejections - 35 USC § 103

Claims 1,8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP-3221095-B in view of JP 2000-107758 or JP 63-028406.

JP-3221095 teaches hollow fiber filters and devices as in claims 1,8 and 10. JP-095 teaches fibrillated structure made of PTFE for support tube and filtration layer as claimed, which is obtained by uniaxial or biaxial stretching, laminating the filtration layer to the support tube, filtration layer of PTFE sheet having smaller pore size than the support layer. The support layer is outside and filtration layer is inside the tube for inside to outside filtration in JP-095. See the text of the reference and the figures.

Applicant's claims differ from the teaching of JP-095 in the recitation of the filtration layer on the outside and support inside for outside-in filtration. However, the

JP-3221095 reference teaches that outside-in structures are known in the art (see paragraphs 0007, 0008), and the teaching of the reference is for specific applications wherein the flow is inside-out. The structure is also otherwise similar – a fibrillated support structure supporting another fibrillated filtration layer. The reference also has an example of a filter with outside filtration layer in the table. The outside-in or inside-out filtration would also be obvious to one of ordinary skill in the art since such types of filtrations with hollow fibers are well known in the art, and one would choose to have the filtration layer facing the fluid to be filtered. References JP 63-028406 and JP 2000-107758 teach outside-in filtration, and both references teach fibrillated porous supports and laminated structures. In JP-406, the filtration layer is on the outside similar to the applicant's claims. In JP-758, there is an additional support for the filtration layer from the outside. One would use the teaching of JP-406 or JP-758 in the teaching of JP-095 depending on the type of fluids to be filtered such as blood or water having high amounts of suspended matter for outside-in filtration.

With respect to the limitations in claim 1 as to the relation between the maximum average fiber length (L), particle size (X), RFL and factor (Y), such a relation at best is an optimization process of selection of the filtration layer pore size to the type of fluid to be filtered (such as the suspended matter particle size) for most efficient filtration, such as maximizing the flux, without increasing filtration layer fouling or pressure drop. For example, consider applicant's comparative example 1. The value of (X) is 0.2 μm, (L) is 15 μm, (L/X) is 75, and the point does not fall within the region defined, as shown in the example. However, for the same filtration layer, if the (X) value were to be 2.0 μm, (L/X) would be 7.5, and it would fall in the region. If the filtration layer could trap 0.2 μm particles to above 90%, it would also definitely trap 2 µm particles to above 90% (Please also see that the claim specifically recites that the pores of the filtration layer are smaller than the pores of the support layer!). Thus, this limitation would reduce to just ***optimizing the membrane (filtration layer) usage*** for a particular particle size for low fouling and high flux. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). This limitation also would be only directed to an intended use of the filtration layer; it is not structurally limiting. A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

Regarding the ratio of pore diameters between the filtration layer and the support layer, see paragraphs 23 and 24 of the reference. Filtration layer pore size is 0.01 – 10 µm; the support pore size can be optimized as indicated in paragraphs 23-25.

Response to arguments of 6/6/07

Applicant's arguments filed 6/6/07 have been fully considered but they are not persuasive.

With respect to the declaration submitted by Mr. Morita, the declaration is not sufficient to overcome the claim rejection. First of all, the claim rejection is not based on inherency, even though the filter of the reference would inherently fall in the region defined in claim 1 for some value of (X). Secondly, the declaration does not provide sufficient details as to how the two filters were manufactured. Paragraph [0024] of the JP-095 reference (see the English translation in file) describes that the PTFE sheet used with the present invention can be manufactured using different types according to pore diameter, porosity, pore structure, thickness, uniaxial or biaxial stretching, etc. The reference JP-095 also teaches making the filtration layer in the same ways. Therefore, it is difficult to believe that one will not be able to make a composite filter using the method of JP-095 that would fall in the region claimed. The cited paragraph teaches that the pore openings can be made “mesh-like” by biaxial stretching, in which case the (Y) value can be tailored pretty close to 1.

It appears to the Examiner that applicant has a correlation, or a test, in which the average of the maximum fibril lengths (L) measured using an SEM is divided by a particle size (X), (X is explained as the nominal pore size of the filtration layer in the response filed 6/6/07), and applicant is optimizing this ratio to fall within a region bounded by certain (X,Y) coordinates to obtain reduced fouling, or reduced flux loss with time. Ideally, one should have square-like (or mesh-like) pores in the stretched filtration layer rather than slit like pores, so that the particles would not be trapped in the pores and cause flux loss. A filtration layer that would pass this test would not be a patentable invention, because many filters available in the market may pass this test. Moreover, applicant’s definition of the test is also indefinite, as is shown in the claim rejection.

With respect to the filter recited in the reference, the JP-095 reference teaches such a filter – see table 1, which has the filtration layer on the outside in example 2, filter B.

(10) Response to Argument

Arguments traversing rejection of claim 1:

Claim interpretation:

Claim 1 Reads:

(a) A porous multilayered hollow fiber for outer side pressed filtration of solid-liquid separation treatment, the filtration being performed from the outer surface side thereof toward the internal surface side, comprising:

(b) a supporting layer constituted of an expanded porous polytetrafiuoroethylene tube (PTFE), and a filtration layer including a porous polytetrafluoroethylene (PTFE) sheet formed by expanding a resin uniaxially or biaxially apart from the supporting layer, the filtration layer being adhered to the outer surface of the supporting layer to form a multilayered body, and pores in the supporting layer three- dimensionally communicating with pores in the filtration layer,

wherein pores surrounded by fibrous frameworks in the filtration layer are smaller than those of the supporting layer, and

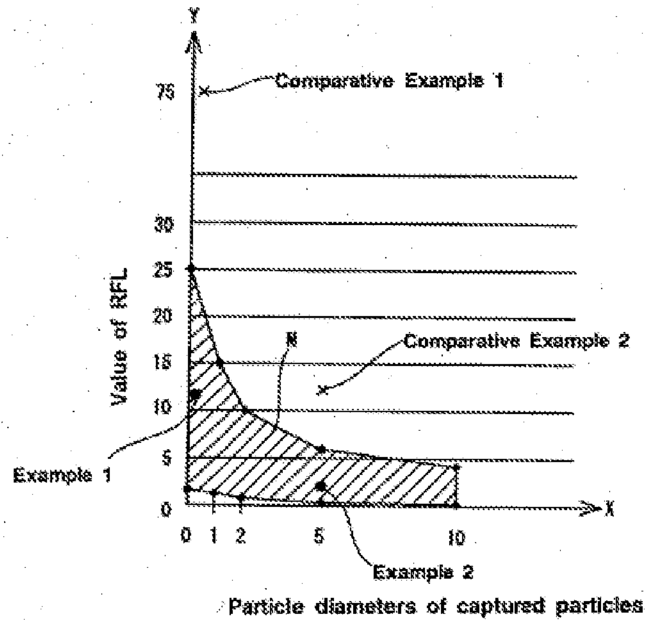
(c) the mean maximum length of pores (L) in the outer surface of the filtration layer is designed such that (X) and (Y) fall within the range defined by plotting the following 10 points on the XY plane, where (X) is a particle diameter of particles captured when the particle trapping ratio is equal to or more than 90 % in the case where the filtration is done under an elevated pressure of 0.1 MPa, and (Y) is a value designated as RFL obtained by dividing (L) by (X), that is, (Y = L/X): (X, Y) = (0.055, 2) (1, 1.5) (2, 1) (5, 0.5) (10, 0.3) (10, 4) (5, 6) (2, 10) (1, 15) (0.055, 25).

[Paragraph numbering (a), (b) and (c) and the underline added by the Examiner]

The preamble of the claim, paragraph (a), recites that the filter is tubular and the direction of filtration is outside-in through the tube wall.

Paragraph (b) recites the actual structure of the filter, which is a double-layer structure; the first layer being the porous PTFE support tube, on to which the filtration layer of uniaxially or biaxially stretched PTFE sheet is wound.

Paragraph (c) recites a region on a graph of (X) vs. (Y), in which the mean maximum length of pores (L) in the outer surface of the filtration layer would fall; the data points for the values of (X) and (Y) being specified in the claim. (X) is defined as **the particle diameter** when the particle trapping ratio is **equal to or more than 90%**. (Y) is defined as (X/L).



Claims 1,8 and 10 are indefinite:

The claims are rejected on two different grounds. First, the claims are indefinite, because the definition of (X) is flawed. It is defined as the particle diameter when the particle trapping ratio is equal to or more than 90%. This definition would not afford a constant value of particle diameter for a specified filter, but would only define any particle diameter that is larger than a certain value that is enough for the filter to trap or remove to 90% or more. Applicant's argument is that characterizing the filter in terms of a particle diameter at 90% trapping ratio is a standard procedure in the industry. The Examiner does not dispute that. However, the claim language should and must be definite. To specify or characterize a filter in terms of a particle diameter, it must be *the smallest* particle diameter that has the trapping ratio of 90% or more. The claim language defines any particle diameter that is trapped 90% or more. Thus any filter would read on this claim language, because all filters will have *a particle diameter* that would be trapped ***90% or more***. (100% trapping ratio is more than 90%). And any filter would have *a particle diameter* that is large enough to make the value of (L/X) fall in the shaded region of the graph (applicant's fig 9, reproduced above) at *a trapping ratio greater than 90%.* Thus the claim reduces to selecting a filter for a specified particle, rather than structurally describing a filter. Applicant's Claim is for a filter, not for the process of selecting a filter. The paragraph (c) of the claim only recites a process of selecting an appropriate filter that would fall on the region of the graph for a particle size (X) to be filtered. And many filters of different pores sizes would qualify. Thus one of ordinary skill in the art would not be able to determine the metes and bounds of the filter claim, and therefore, it is indefinite.

The argument (page 5 of the brief):

> "For example, on page 2 of ROT FILTER there is a specification table which identifies different filter grades/models (e.g., ROT-7HCS, ROT-10HCS, etc.) based on the industry standard of removing 5 µm particles over 90% (notwithstanding the possibility that particles greater than 5 µm may also be removed). Similarly, on page 4 of the English translation of the tables in the Kuraray article, a table entitled "Basic Performance of Kuraray Hollow-Fiber Membranes" lists various filter grades based on a 90% trapping ratio for a set particle diameter (e.g., SF-301(0.04 µm), SF-401(0.10 µm), etc.)(two published technical specifications of Kuraray filters indexed in terms of the 90% trapping ratio also enclosed for the Board's reference). In this regard, it is noted that "resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention," *Verve v. Crane Cams*, 65 USPQ2d 1051 (Fed. Cir. 2002)."[Emphasis by Applicant]

is not persuasive because the evidences provided only shows the micron rating of the filters specified. **They fail to provide any definition for the "micron rating".** Examiner submits that the micron rating of a filter is defined as the smallest diameter of particles that the filter can remove to a specified efficiency, such as 90%. Thus "5 µm at 90%" means that the smallest particle that filter can remove at 90% efficiency or more is 5 µm. Applicant has not met the extrinsic evidence requirement of the quoted case law.

Claims 1, 8 and 10 are not patentable over the prior arts:

The second ground of rejection is on merits based on prior arts. In here, it was shown that the filter structure as claimed is obvious over the cited references, which the applicant does not seem to dispute. The primary reference cited teaches the filter structure, that is, a filter having a porous PTFE support tube and a uniaxially or biaxially stretched PTFE filtration layer on the support. The difference is that the reference teaches an inside-out filter with the filtration layer on the inside of the PTFE support tube. However, applicant admits that outside-in filtration with filter layer on the outside surface of the PTFE tube is well known. The primary reference also teaches that it is known. Secondary references supporting this knowledge is also provided. And applicant also does not dispute this.

Please note that the reference JP-095 actually teaches a filter with the filtration layer outside the support tube in the product (B) - see paragraph [0034] at page 10 of the English translation, and Table 1. This would make this reference a 102(b)/103(a) reference - inherency. From the definition of the (X) and (Y) values, this filter with the outside filtration layer also would inherently have a value of particle diameter (X) that would be trapped more than 90% and which would fall in the region (Y) as claimed!

Applicant's only contention is with respect to the paragraph (c) of the claim. The question to be answered here is whether this paragraph defines a patentably distinguishable structure to the filtration layer? The Examiner strongly believes that it does not. Arguendo, the claim language is assumed to be reciting (X) as the smallest diameter of the particle that would be trapped 90% or more by the filter, or a particle diameter that would be trapped exactly at 90%. Even then, paragraph (c) of the claim only recites a process of selecting a filter. It does not impart a distinguishable structure to the filter. The Examiner submits that there can be a lot of PTFE filters existing that would fall in this group.

Applicant's disclosure also does not teach any specific structure or method of making that would impart a specific structure associated with the definition of paragraph (c). The filtration layer (surface) pores are obtained by uniaxially or biaxially stretching the filtration layer. This is well known in the art. The cited references teach this process of making. There are no special steps or process conditions described in the specification that can be attributed to a unique filter structure, or can be considered as unique or catalyzing or modifying the filter formed to have a unique structure that would make the filtration surface behave in the manner recited in paragraph (c). All that paragraph (c) does is sort from the filters available the one that fits the need of having a particle diameter (X) that would make the measured (L) of the filter fall in a range. Thus the claim is not patentable.

Applicant has not provided a structure, or a process condition or process step of making or modifying the filter, that would make the resulting filter fall within the range specified in paragraph (c) with some or any degree of a certainty. What is claimed is only sorting or selecting an existing filter for a purpose.

The declaration submitted by Mr. Morita is grossly inadequate to prove anything. At step 7 of the declaration, Mr. Morita states that he had made two filters according to the method disclosed in JP'095, and then proceeds to show data points of samples 1 and 2 for values of "X" and "L", which do not fall in the region of the graph of fig 9.

However, the JP'095 patent describes several alternate methods of making, such as by uniaxial or biaxial stretching, etc., and starting with filters of different pore diameters (see paragraph 24). It is the surface of the filtration layer that is controlling, and this surface is formed by stretching the film. Applicant's disclosure is also identical in terms of making the filtration layer, except for the filtration layer being external to the tube instead of internal to the tube as in the reference.

The declaration only shows that the filters Mr. Morita tested according to the requirement of paragraph (c) of claim 1 did not pass. This would not make the claim patentable. In fact, the possibility exist that one of ordinary skill in the art trying to make the filter as claimed may never succeed in making it, because the process is totally random. If one follows the teaching of applicant's specification and make the filter, then test it using the SEM methods to measure the value of "L", test it to find the smallest particle size that it would trap 90% or more, and then try to fit the data on the graph of fig 9, what is the guarantee that it would fit? None! Because the specification lacks a step or steps in the process of making the filter that would provide such a guarantee. On the contrary, if the process described would make the filter as recited in claim 1, then so would the filter of the JP’095 reference. There is also no showing that the filtration layer on the outside actually makes the difference (in such a case the reference would be anticipatory, because of the product B).

Arguments regarding the result-effective variable: these are not commensurate in scope with the rejection or claims. These variables would not make the claims patentable. They have nothing to do with the filtration layer structure; they are only parameters coined by the inventor/applicant for the filter selection process. The explanation in the claim rejection was in response to applicant's arguments traversing the rejection, that the claimed limitation in paragraph (c) can be best described as only an ***optimization process for membrane usage***. X and Y were assumed to be result-effective variables that can be used to optimize the filter usage (or, selection) for low fouling and high flux.

Claim 6 is Allowed:

Rejection of claim 6 is hereby withdrawn, and claim 6 is allowed, based on the argument that the outer surface of the porous expanded PTFE tube was afforded unevenness of 20-200 μm by flame treatment, laser irradiation or plasma irradiation.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Krishnan S Menon/

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